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EXAMINER	
RAO, DEEPAK R	
ART UNIT	**PAPER NUMBER**
1624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,489	SERGEEVA ET AL.	
	Examiner	Art Unit	
	Deepak Rao	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20050411, 20060509 & 20060724*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-17 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds Compound #2; NB3024; NB3057; NB3068 and NB3103 (disclosed in pages 7-8 of the specification), does not reasonably provide enablement for a compound represented by the structure in claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed. The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations.

The specification fails to enable the preparation of the entire scope of the claimed compounds. The description and examples provided in the specification at pages 7-8 are drawn to specific compounds having a specific "Linker" and "Toxin" groups, however, there is no disclosure of the sources of starting materials needed to prepare for all of the compounds of the structure of claim 1, wherein 'Linker is either absent or is a traceless linker'; and 'Toxin is an agent that is toxic upon activation by an activating enzyme'. Further, the description of the terms in the claim appears to represent a 'product by process' claim due to the presence of the functional language.

The specification provides examples of certain compounds (see pages 7-8) represented by the structure depicted in claim 1 which contain specific 'Linker' and 'Toxin' groups. The specification, however, does not provide any explanation or sources of all types of 'Linker' or 'Toxin' groups such that a person of ordinary skill could determine if a particular group is suitable to be a linker and/or a Toxin for the claimed structural formula. The claim merely recites that 'Toxin is an agent that is toxic upon activation by an activating enzyme', however, the specification does not provide guidance as to what is encompassed by the recitation in the claim. Further, the definitions of other variables of the structure contain extremely broad definitions. See for example, the definition of B_2 wherein it is recited that 'when B_2 is $-N(R_{12})-$ or $-C(R_{13})(R_{14})-$ it can be additionally joined through R_{12}, R_{13} or R_{14} to R_4 or R_5 to form a cyclic structure'. Claims 9 and 11 provide some specific groups intended to represent the term 'Toxin', however, contain open-ended statements such as "derivative" and "analog" or "analogues". The specification does not sufficiently describe synthetic procedures with the necessary starting

compounds and reagents to prepare such embodiments encompassed by the instant claims; nor such embodiments are illustrated via examples.

In view of the lack of direction provided in the specification regarding starting materials, the lack of working examples and the general unpredictability of chemical reactions, it would take an undue amount of experimentation for one skilled in the art to make the claimed compounds and therefore practice the invention. The starting material sources necessary to obtain the instant compounds must have been available as of the filing date in order to provide an enabling disclosure. See *In re Howarth*, 654 F.2d 103, 210 USPQ 689 (CCPA 1981); *Ex parte Moersch*, 104 USPQ 122 (POBA 1954). Applicants should show that the sources of these starting materials was common knowledge or readily available at the time of filing.

2. Claims 15-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a subject having the symptoms of an infection due to the specific microorganisms listed in Tables 3 and 4, does not reasonably provide enablement for a method for inhibiting the growth of microorganism generally; a method for treating a subject generally; or a method for identifying potential therapeutic agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working

examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed. The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations.

The instant claims 15-17 appear to be 'reach through' claims. Reach through claims, in general have a format drawn to mechanistic, receptor binding or enzymatic functionality and thereby reach through any or all diseases, disorders or conditions, for which they lack written description and enabling disclosure in the specification thereby requiring undue experimentation for one of skill in the art to practice the invention.

The use disclosed in the specification for the compounds is 'for alleviating the symptoms of an infection by a microorganism in a subject by administering an effective amount of the compound'. The instant claims, however, are drawn to broad methods of inhibiting microorganisms; treating generally or identifying therapeutic agents. The broadest interpretation of the terms instant claims without limitation reads on many and all types microorganism, or therapeutic methods or therapeutic agents.

The instant claim 16, is drawn to 'a method of treating a subject', however, it is not recited 'what is being treated in that subject' and if the claim is intended for 'a method of treating a disease or an infection in the subject'. The claim language covers any and all types of therapeutic methods and the specification does not sufficiently enable the instantly claimed method.

Test assays and procedures to determine the biological activity of the compounds with respect to a specific microorganisms are provided in Examples 20-22 of the specification.

However, there is nothing in the disclosure regarding how this *in vitro* data correlates to the treatment of all types of therapeutic methods encompassed by the instant claims. Further, there is no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. Note *In re Surrey*, 151 USPQ 724 regarding sufficiency of disclosure for a Markush group.

Further, there is no disclosure regarding how the patient in need of the specific treatment is identified and further, how all types of infections due to microorganisms generally are treated. See MPEP § 2164.03 for enablement requirements in cases directed to structure-specific arts such as the pharmaceutical art. Receptor activity is generally unpredictable and highly structure specific area, and the data provided of the single compound is insufficient for one of ordinary skill in the art in order to extrapolate to the other compounds of the claims. It is inconceivable as to how the claimed compounds can treat the extremely difficult diseases embraced by the instant claims.

No compound has ever been found that can treat infectious disorders due to microbial organisms generally. Since this assertion is contrary to what is known in medicine, proof must be provided that this revolutionary assertion has merits. Nearly all drugs for treating infections are effective against only a limited group of disorders. Therefore, a compound effective against all types of microorganisms generally would be a revolutionary exception. It is well established that an enablement rejection is proper when the scope of enablement is not reasonably correlated to the scope of the claims. (*In re Vaeck*, 20 USPQ2d 1439, 1444 (CAFC 1991); *In re Ferens*, 163 USPQ 609).

Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical use of the instant compounds. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved". See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(Only a few of the claimed diseases are discussed here to make the point of an insufficient disclosure, it does not definitely mean that the other diseases meet the enablement requirements). There is no evidence of record, which would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the disease(s) or disorder(s) claimed herein.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

1) The nature of the invention: The 'methods of use claims' are drawn to inhibiting all microorganisms or treating any and all microbial infections, etc. Currently, there are no known agents with the chemotherapeutic efficacy to prevent microbial infections generally. The art does not disclose an active agent or combination of active agents, which is recognized to prevent the conditions cited supra. The prior art does not teach or disclose a treatment modality wherein

healthy subjects are administered an active agent or agent(s) and there is evidence that none of the associated symptoms or disease state characteristics are ever manifested.

2) The state of the prior art: There are no known compounds of similar structure which have been demonstrated to treat or prevent all of the diseases due to microbial infections. Some of the state of the art reference statements are provided below to show the unpredictability of the art:

3) The predictability or lack thereof in the art: It is presumed in the treatment of the diseases and/or disorders claimed herein there is a way of identifying those people who may develop any kind of the infection. There is no evidence of record that would enable the skilled artisan in the identification of the people who have the potential of becoming afflicted with the infections intended herein. Applicants have not provided any competent evidence or disclosed tests that are highly predictive for all the instantly claimed methods of treatment or method for identifying of the therapeutic agents. Therapeutic treatment of microbial infections depends on many differing effects of factors such as endemic pathogens, underlying diseases, and antimicrobial prescribing habits.

4) The amount of direction or guidance present and 5) the presence or absence of working examples: There are no doses present to direct one to protect a potential host from the microbial infections. The examiner notes, there is not seen sufficient guidance provided in the form of administration profiles, combination ratios of the active agents or references to same in the prior art to provide the skilled artisan with sufficient guidance to practice the instant method of therapeutic or preventive treatment. The data and evidence provided in the instant disclosure leads the examiner to doubt the objective truth of assertions of the methods of instant claims.

Many microorganisms have mechanisms that impair antibody production at different sites by inducing suppressor cells, blocking antigen processing, and inhibiting lymphocyte mitogenesis.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). There is not seen in the disclosure, sufficient evidence to support applicant's claims of inhibiting and therapeutic activity of the instant claims. The Test Examples 20-22 all relate to determining the inhibitory effects of the compounds against bacterial growth. There is not seen sufficient working examples or data from references of the prior art providing a nexus between that which applicant asserts as proof of a method for inhibiting microorganisms generally; a method of treating generally; or a method of identifying therapeutic agents generally; or extrapolation from the data and evidence currently provided on the record to support the claimed methods.

6) The breadth of the claims: The claims are drawn to inhibiting microorganisms generally or therapeutic treatment generally, including treatment of all microbial infectious disorders that are not related. The entire scope of the biological activity recited in the instant claims is generally is unknown.

7) The quantity of experimentation needed would be an undue burden to one skilled in the pharmaceutical arts since there is inadequate guidance given to the skilled artisan, regarding the instantly claimed methods.

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the instant case for the instant method claims. In view of the breadth of the claim, the chemical nature of the invention, the unpredictability of ligand-receptor interactions in general, and the lack of working examples regarding the activity of the claimed compounds, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

1. Regarding claim 1, the phrase(s) "**for example**"; "**etc.**", "**such as**" (where ever present, all occurrences, through all the claims) render the claims indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).
2. In claim 1, in the definition of B_2, the recitation: 'wherein the fragment $-B_2-C(R_4)(R_5)-C(=A_3)-$ in its entirety is proline or a proline derivative or analog' is not in alternative form. In the claim B_2 is defined to be 'absent or selected from –O-, -S-, ….', following which it is also recited that 'the fragment $-B_2-C(R_4)(R_5)-C(=A_3)-$ in its entirety is proline', which appears to be intended as an alternative definition.

3. In claim 1, in the definition of B_2, in the recitation "proline **derivative** or **analog**", the terms "derivative" and "analog" are indefinite. The above recitations do not set forth the metes and bounds of the terms intended for B_2 and clearly provide what groups are intended by the recitations. For example, the term "**derivative**" may be interpreted as a residue derived from the compounds or a modification to the compounds recited in the claims, and it is confusing which compounds are derived from or modified to, from the other ingredients or compounds recited in the claims. The discrepancy is repeated in claim 9, in the recitation – "nitrogen mustard and the **derivatives, analogues**"; and in claim 11, in the recitation – "norfloxacin or a **derivative, analog**".
4. Claim 1, does not clearly set forth the definitions of the terms "Linker" and "Toxin". The claim does not set forth the intended representative groups for these terms but recites a reaction step involved in a process. It appears that the claim is in a 'product by process' format.
5. Claim 3 recites the limitation "**X is** selected from the group consisting of oxygen, sulfur or **methyl**" in lines 1-2. There is insufficient antecedent basis for this limitation in claim 1 on which claim 3 is dependent (via claim 2). Claim 1 defines X to be a divalent ' CH_2 ' group which is different from the instant recitation of "methyl" which represents "-CH_3".
6. Claim 6 recites the limitation "**B_1 is -NH**" in line 1. There is insufficient antecedent basis for this limitation in claim 1 on which claim 6 is dependent (via claims 2-5). Claim 1 defines B_1 to be a divalent ' –NH- ' group and claim 6 recites a monovalent group '-NH'.
7. Claim 12 does not further limit claim 1.

8. Claim 15 recites 'a method for inhibiting the growth of microorganism', however, the claim does not set forth how this method is administered. The claim does not clearly set forth if the claim is intended as 'a method for inhibiting microorganism in a subject by administering the effective amount of the compound'.
9. Claim 16 recites 'a method for treating a subject', however, the claim does not clearly set forth what is being treated in the subject.
10. Claim 17 recites 'a method for identifying potential therapeutic agents, comprising (a) contacting a microorganism with a compound of claim 1', however, the claim does not set forth how this method is administered. The claim does not clearly set forth where the method is carried out.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-17 are rejected under 35 U.S.C. 102(a) as being anticipated by Sergeeva et al., XP008064894 (2002). The instant claims read on reference disclosed compounds, see the series of compounds of the formula N-formyl-Met-Leu-Linker-prototoxophore in the reference.

   Note: Applicant cannot rely on the priority benefit based on U.S. Provisional

Application 60/374,089 filed April 18, 2002 to overcome the rejection. The provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for the instant claims, see for example, the definition of B_2 wherein the instant claims recite that 'when B_2 is $-N(R_{12})-$ or $-C(R_{13})(R_{14})-$ it can be additionally joined through R_{12}, R_{13} or R_{14} to R_4 or R_5 to form a cyclic structure'. The priority application does not contain the above limitation.

2. Claims 1 and 12-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Berger et al., U.S. Patent No. 4,469,789. The instant claims read on reference disclosed compounds, see the compounds of the formula (I) in col. 2 and the corresponding species of the examples, e.g., the compound 3.36 in col. 16.

3. Claims 1 and 12-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Bajusz et al., U.S. Patent No. 4,339,440. The instant claims read on reference disclosed compounds, see the compounds of the formula (I) in col. 1 and the corresponding species of the examples, e.g., the compound of Example 2 in col. 8.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 7,163,923. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the reference claims substantially overlap. The reference teaches a generic group of compounds useful as inhibitors of microorganisms. The instant claims generically overlap the reference claims. It would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species or subgenus of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole i.e., as therapeutic agents. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole.

Duplicate Claims

Applicant is advised that should claim 1 be found allowable, claim 12 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application

are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 12 merely recites 'a purified form of the compound of claim 1', however, does not further limit the base claim because the compounds according to claim 1 are assumed to be in pure form.

Receipt is acknowledged of the Information Disclosure Statements filed on April 11, 2005; May 9 and July 24, 2006 and copies are enclosed herewith.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Monday-Friday from 8:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Deepak Rao/
Primary Examiner
Art Unit 1624

September 20, 2007